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Kenneth

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(54) FLUOROSCOPY-FREE GUIDEWIRE SYSTEMS AND METHODS

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(2), (4) Date: **May 17, 2007**

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(51) **Int. Cl.**
A61B 6/00 (2006.01)

(52) **U.S. Cl.** ... **600/434**; 600/104; 600/424; 604/164.13; 606/151

(58) **Field of Classification Search** 600/424, 600/104, 434; 128/899; 604/164.13; 606/151
See application file for complete search history.

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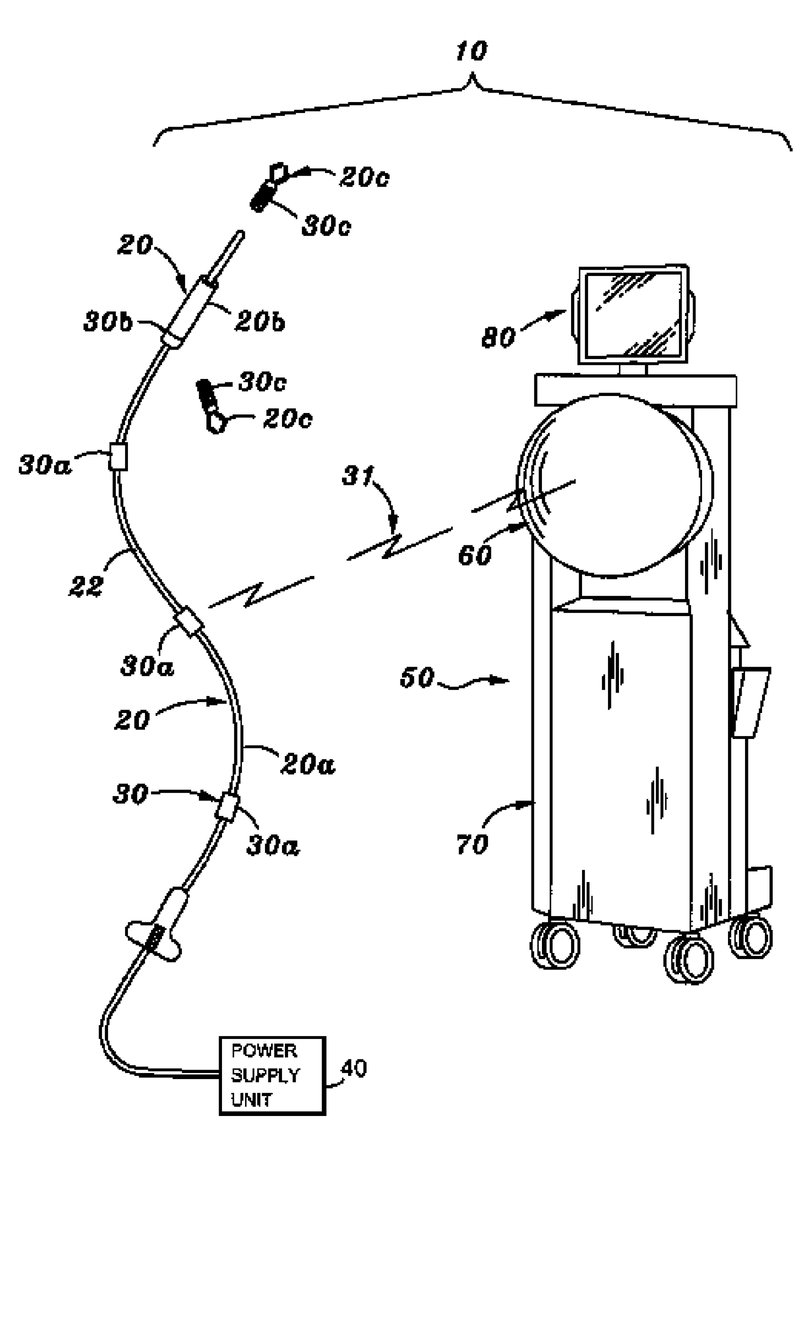
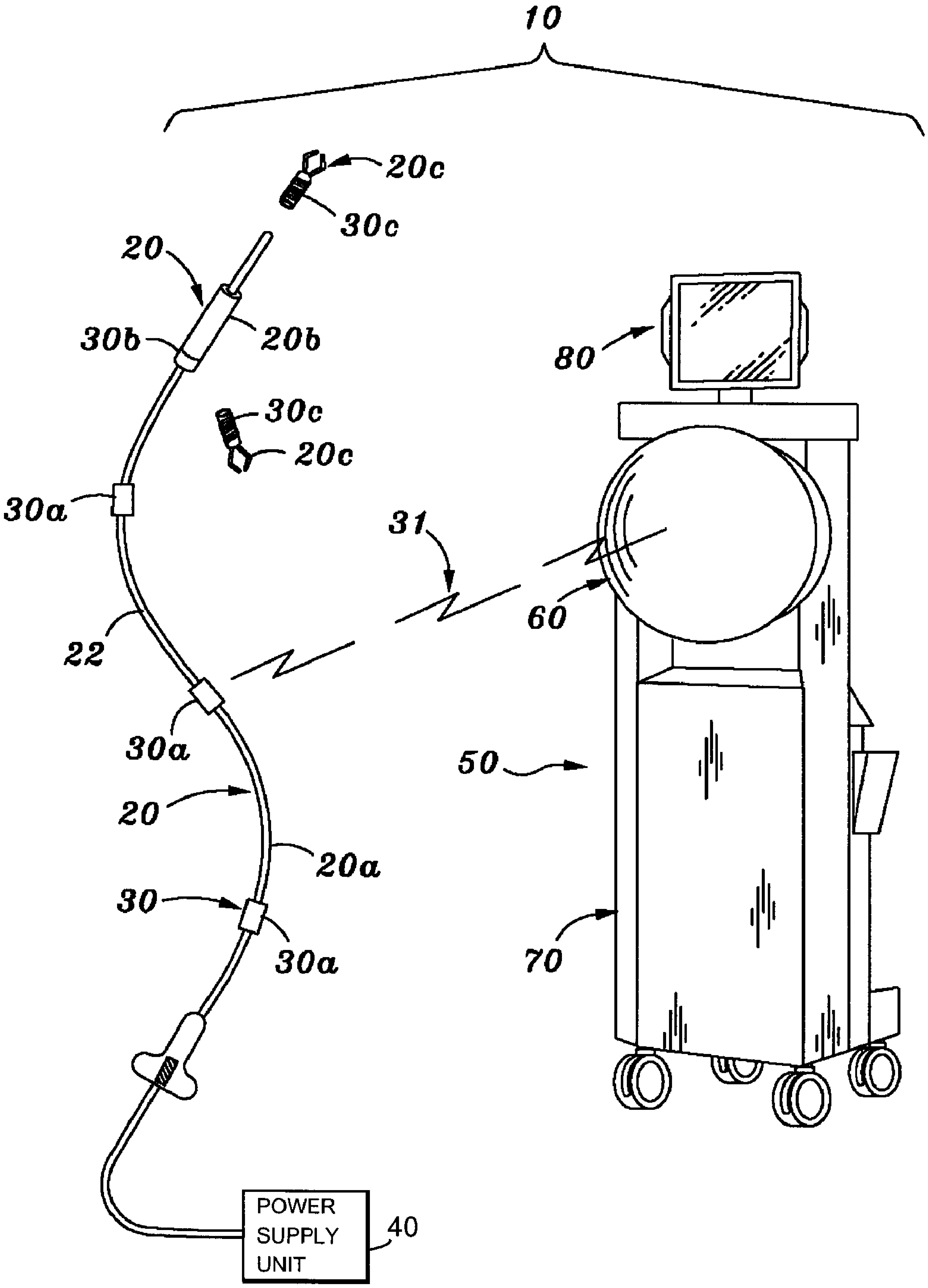
(57) **ABSTRACT**

A system (**10**) includes electromagnetic indicator coils (**30**) included in surgical devices, examples of surgical devices (**20**) including guidewires; surgical instruments including dilators, stents, catheters, jejunostomy tubes, and endoscopes; and indicator clips (used for marking a location within patient). An innovative device indicator is attachable to any surgical instrument to convert it to an electromagnetically monitorable instrument. A monitoring unit (**50**) detects electromagnetic fields from the electromagnetic indicator coils and displays the location and configuration of the electromagnetic indicator coils on a display unit (**80**). The relative positions and overall configuration of multiple devices—such as guidewires, instruments, and location marker indicator clips—can all be simultaneously electromagnetically monitored with the use of radiology.

14 Claims, 6 Drawing Sheets

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20c
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30
30a
70
POWER
SUPPLY
UNIT
40

FIG. 1

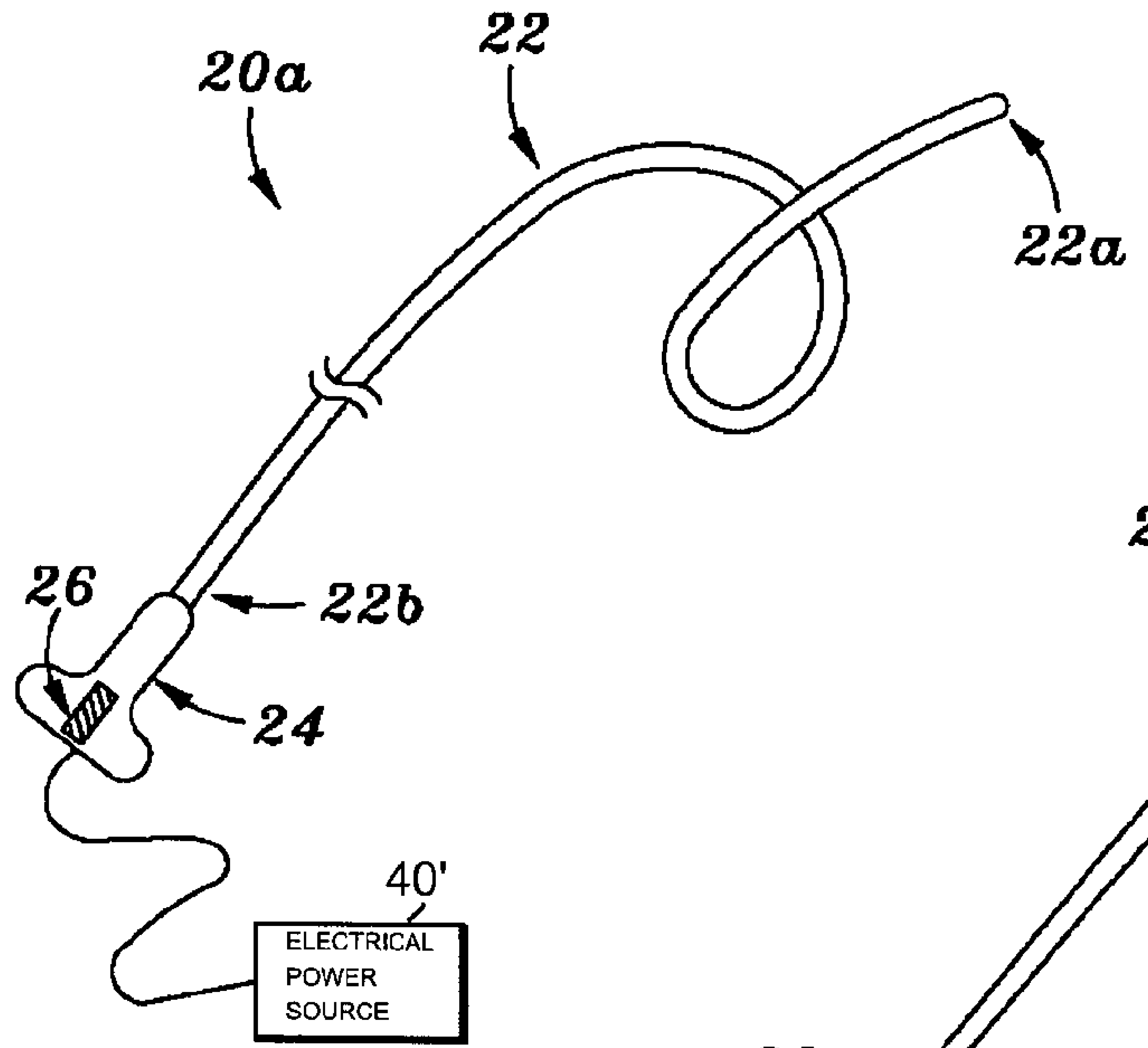

FIG. 2A

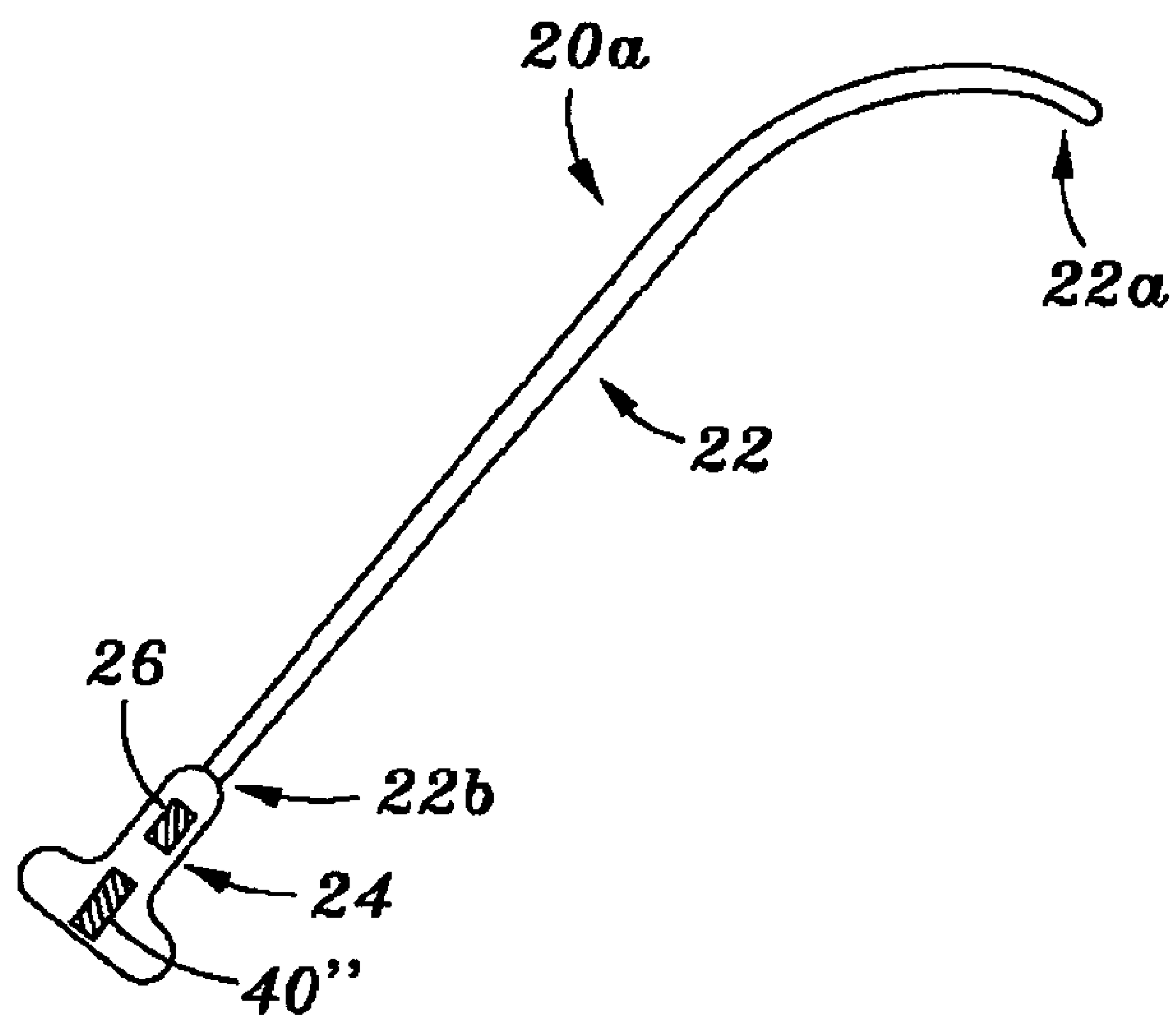

FIG. 2B

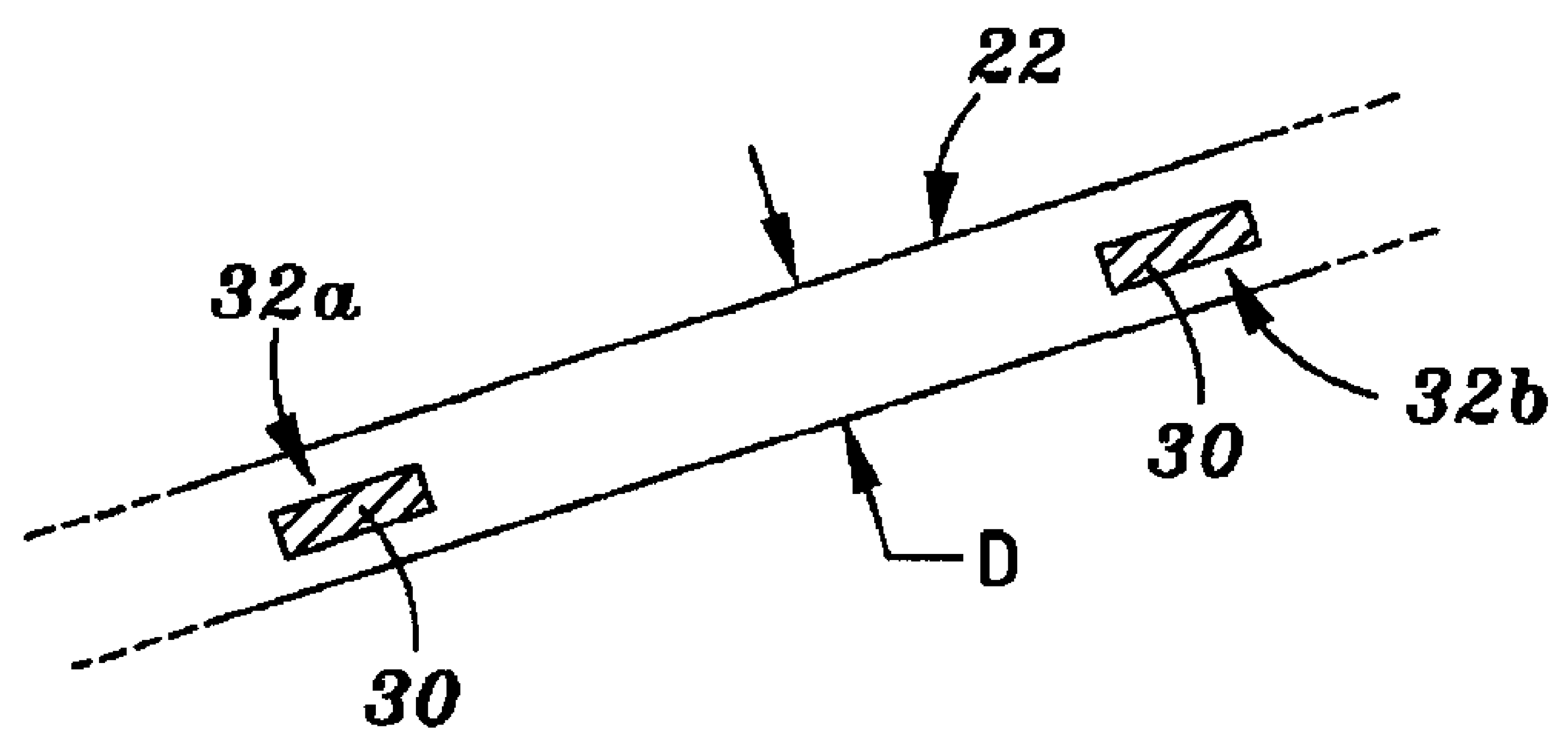

FIG. 3

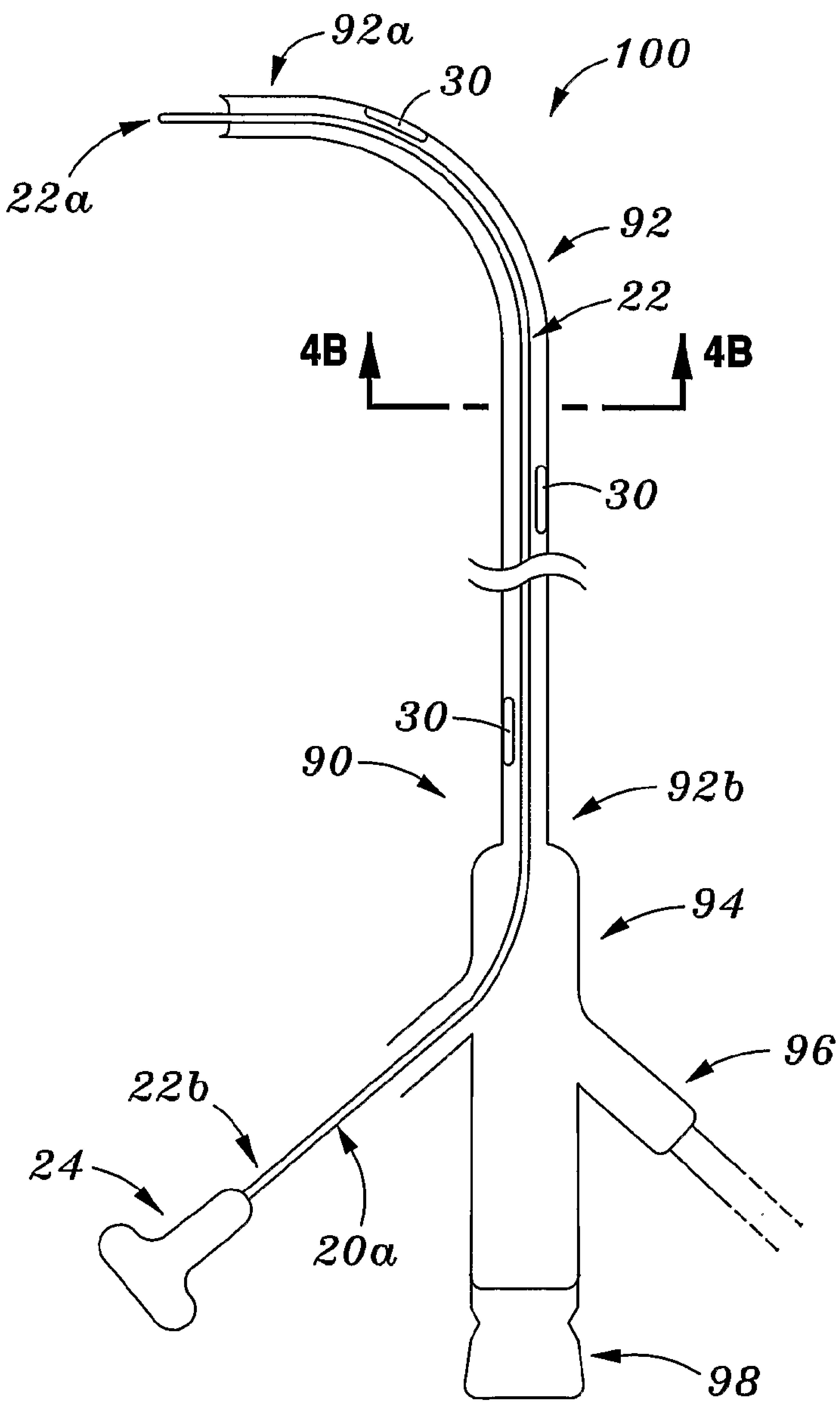

FIG. 4A

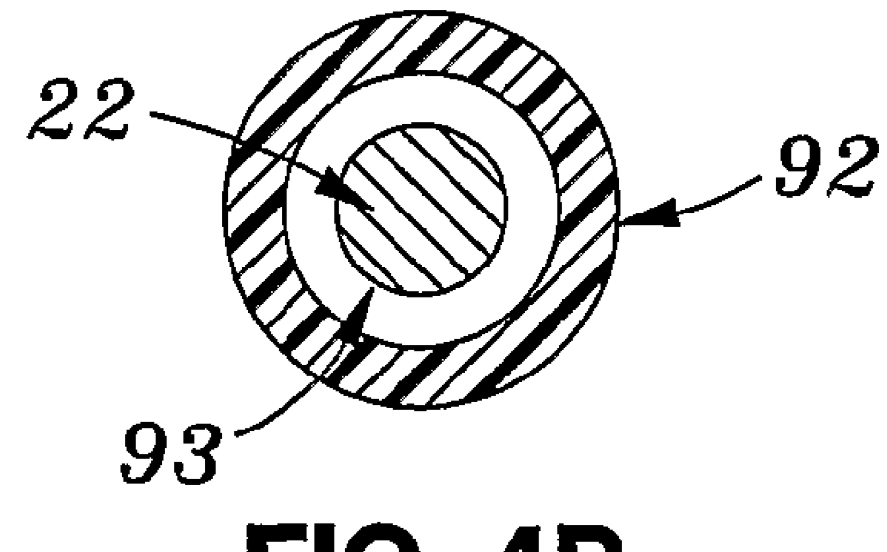

FIG. 4B

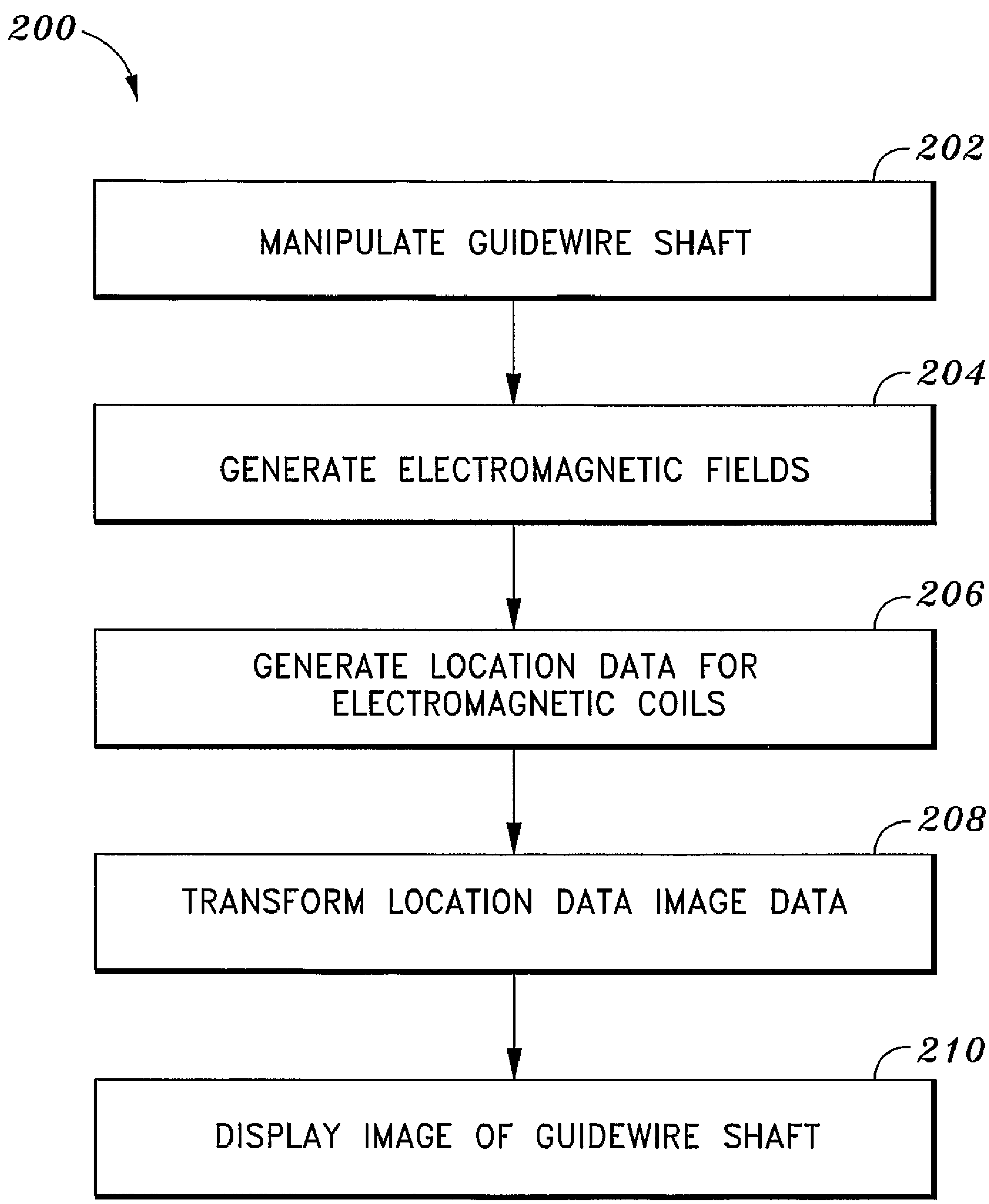
200
202
MANIPULATE GUIDEWIRE SHAFT
204
GENERATE ELECTROMAGNETIC FIELDS
206
GENERATE LOCATION DATA FOR ELECTROMAGNETIC COILS
208
TRANSFORM LOCATION DATA IMAGE DATA
210
DISPLAY IMAGE OF GUIDEWIRE SHAFT

FIG. 5

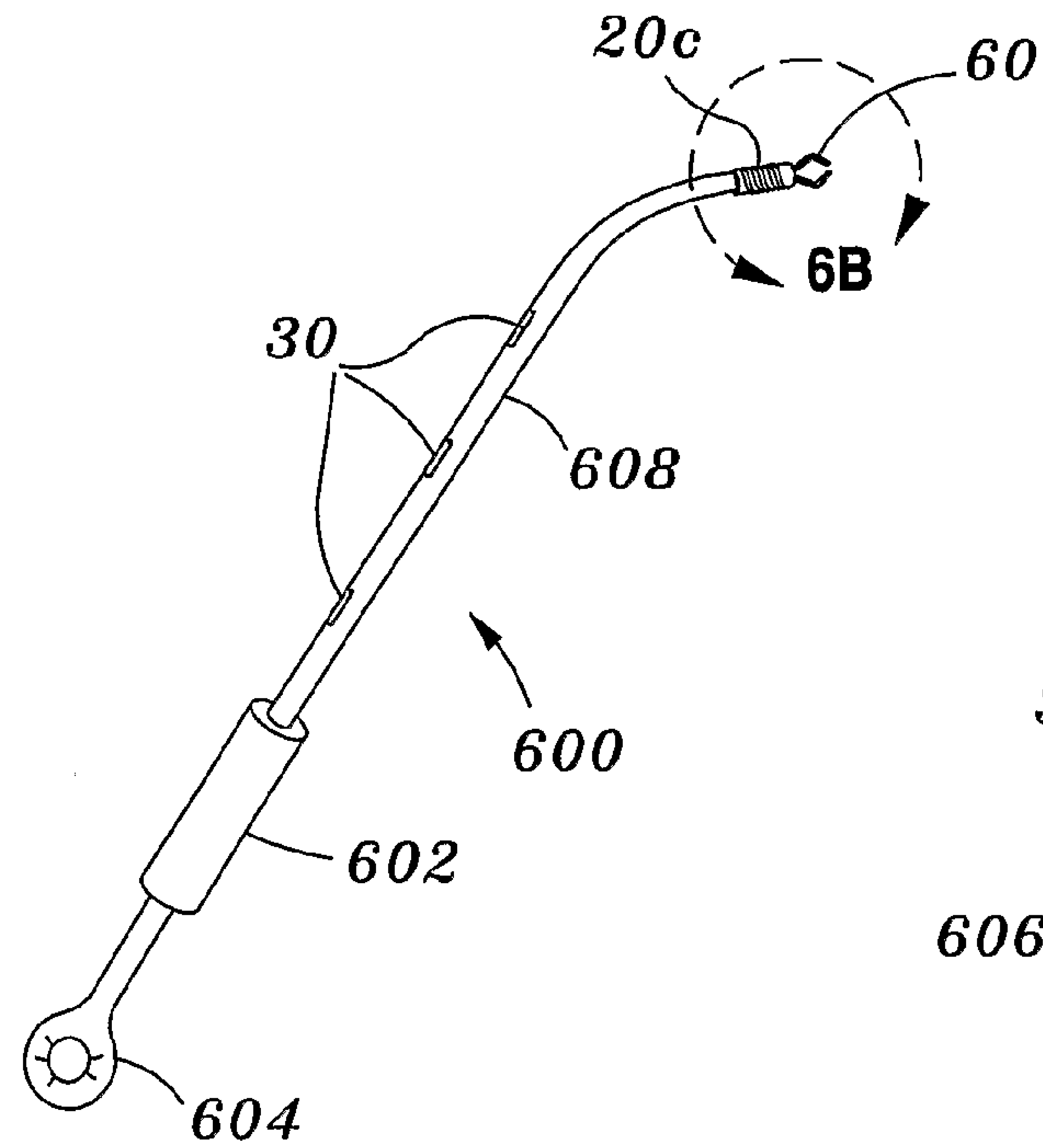

FIG. 6A

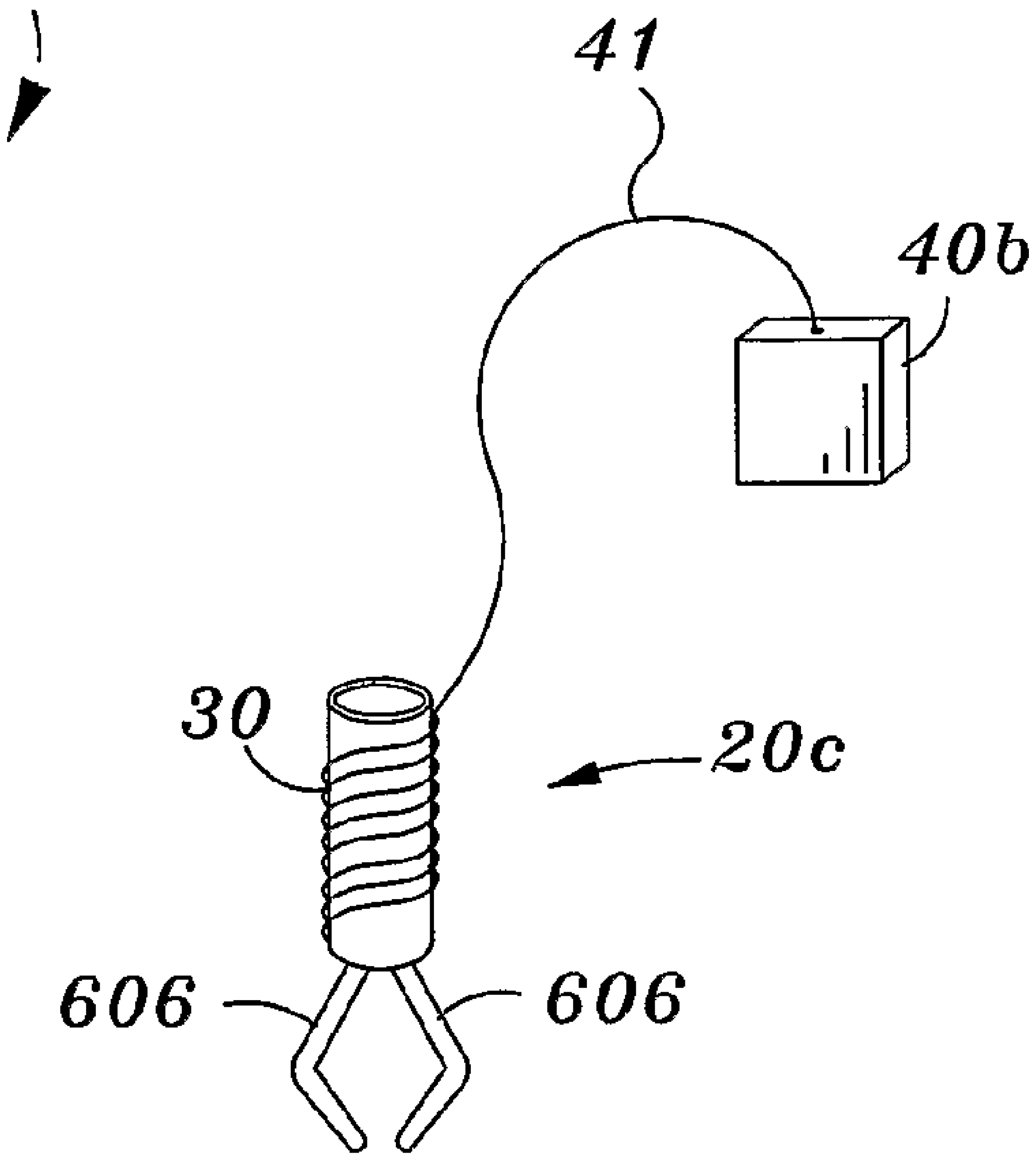

FIG. 6B

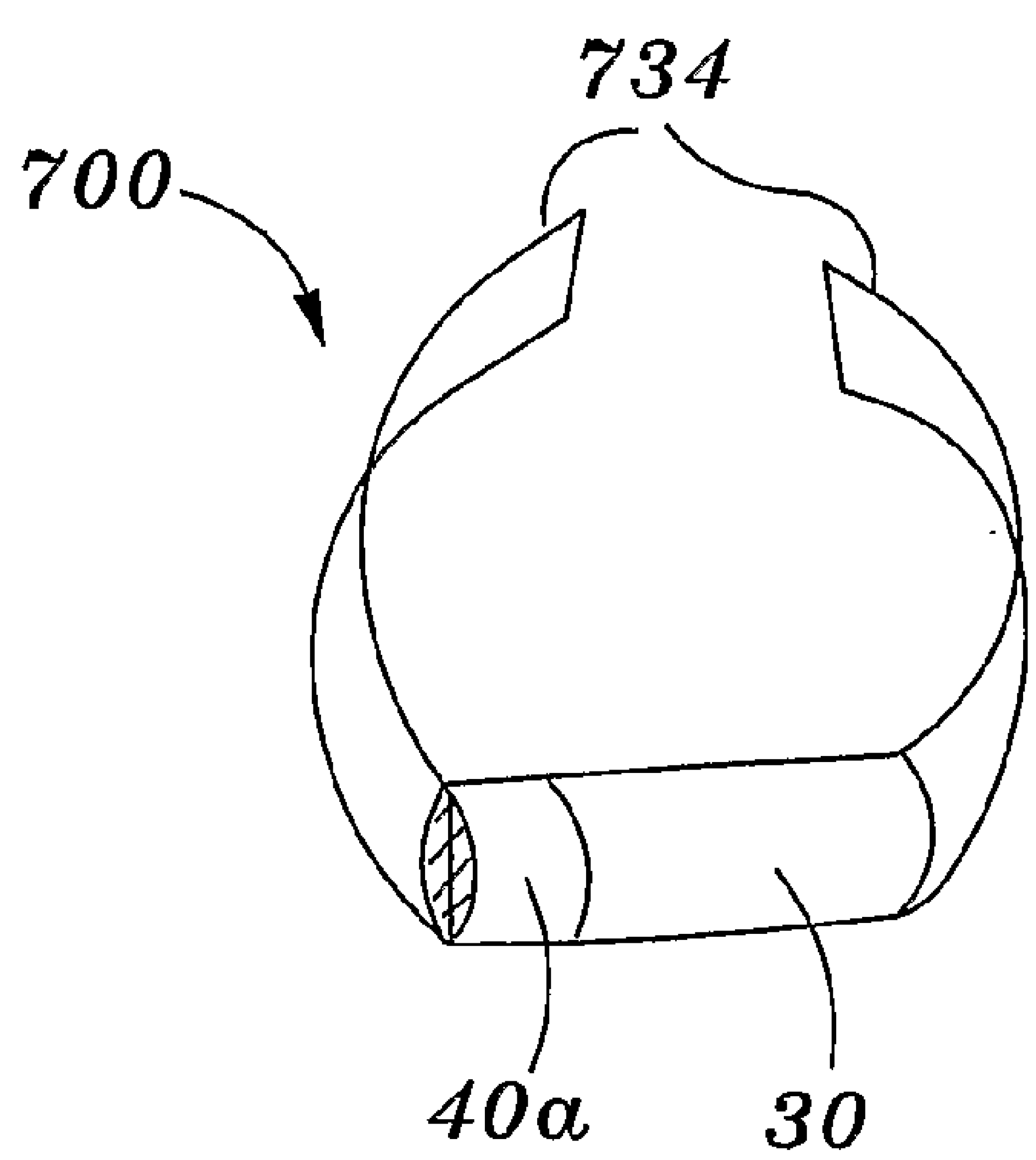

FIG. 7A

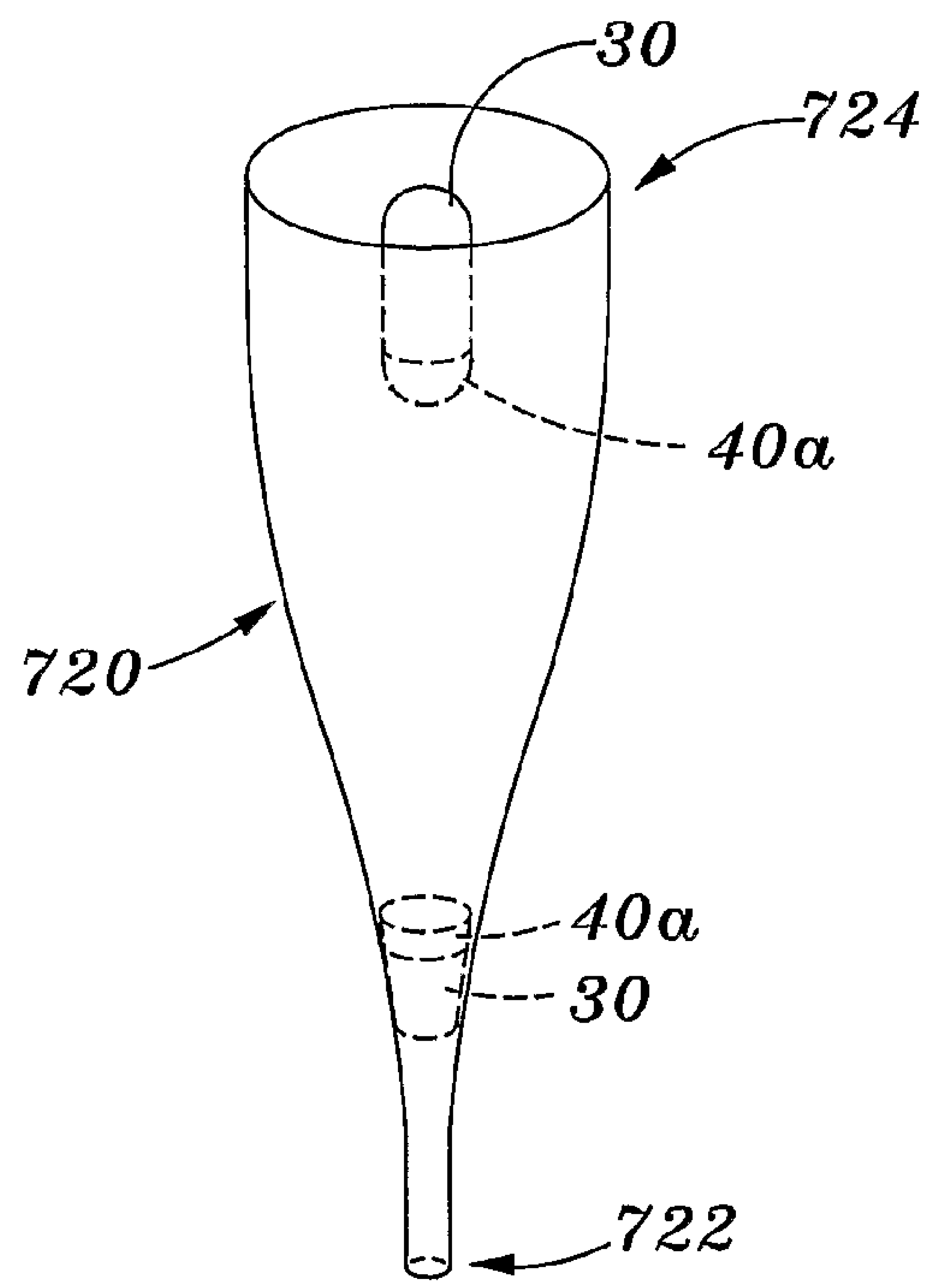

FIG. 7B

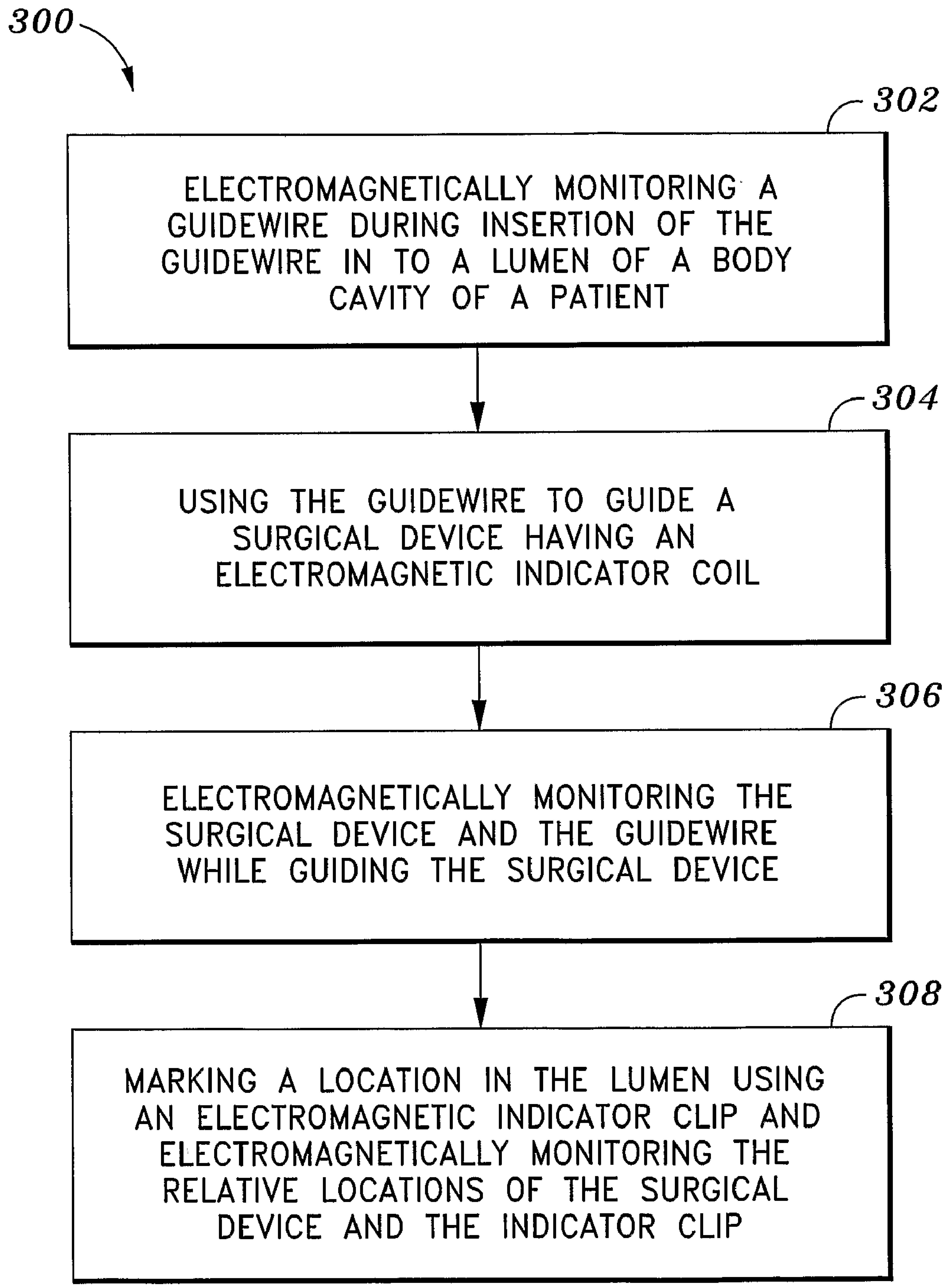
300
302
ELECTROMAGNETICALLY MONITORING A GUIDEWIRE DURING INSERTION OF THE GUIDEWIRE IN TO A LUMEN OF A BODY CAVITY OF A PATIENT
304
USING THE GUIDEWIRE TO GUIDE A SURGICAL DEVICE HAVING AN ELECTROMAGNETIC INDICATOR COIL
306
ELECTROMAGNETICALLY MONITORING THE SURGICAL DEVICE AND THE GUIDEWIRE WHILE GUIDING THE SURGICAL DEVICE
308
MARKING A LOCATION IN THE LUMEN USING AN ELECTROMAGNETIC INDICATOR CLIP AND ELECTROMAGNETICALLY MONITORING THE RELATIVE LOCATIONS OF THE SURGICAL DEVICE AND THE INDICATOR CLIP

FIG. 8

FLUOROSCOPY-FREE GUIDEWIRE SYSTEMS AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/609,501 filed 13 Sep. 2004.

BACKGROUND OF THE INVENTION

The present invention generally relates to surgical procedures and, more particularly, to positioning and monitoring the position and configuration of surgical implements.

Endoscopes are well known in the field of medicine. Endoscopes with a soft insertion unit can be inserted into the lumen of a body cavity to diagnose problems located in a deep region in the body cavity without the necessity of incision and can also be used to guide treatment appliances to a desired location within the body cavity. In the past, medical practitioners have needed to use radio-opaque markers or contrast either in the patient or on the instruments (or both) in order to visualize instrument placement under fluoroscopy. In cases where x-ray exposure under fluoroscopy is contra-indicated or where the scheduling of procedures to occur in radiology is economically or logistically discouraging, alternative measures are needed that can substitute, for example, for injecting contrast into the gastrointestinal (GI) tract in order to "tattoo" a certain area which can be visualized on fluoroscopy; or for indicating the location of existing endoscopes or accessory devices—such as a stent deployment catheter, a Stretta radiofrequency catheter, or a dilator. One such accessory device is a clip that can be used, for example, to hold portions of tissue together. The clip can be inserted into the body cavity using a clip fixing device available, for example, from Olympus Corporation (Tokyo, Japan), Wilson-Cook Medical, Inc, (Winston-Salem, N.C., US), and Boston Scientific Corporation (Natick, Mass., US).

When inserting, for example, an endoscope, a guidewire, or clip fixing device, each of which includes a long flexible tube, it is possible for the tube to bend back on itself or form a loop or enter some other undesirable configuration. An endoscope, for example, typically has a steerable end that can be curved in different directions under the control of the operator and it is useful for the operator to know whether the configuration of the endoscope end is achieving a desired position and whether a position of a treatment appliance—such as a dilator, stent, or clip—relative to the position of the endoscope—for example, in some cases the appliance may be passed through the endoscope—is as desired. In the past fluoroscopy has been used to monitor the configuration of endoscopes. Recently, a colonoscope, which is a particular type of endoscope, known as ScopeGuide™ and marketed by Olympus Corporation, Tokyo, Japan, has electromagnetic coils which allow visualization of the colonoscope configuration on a monitor. A system for detecting the shape of an endoscope using source coils and sense coils via a detection system having a processor included in a control unit is disclosed in U.S. Patent Application Publication No. 20030055317, assigned to Olympus Optical Co., and incorporated by reference.

As can be seen, there is a need for positioning a variety of surgical instruments and monitoring the positions and configurations of those instruments while providing an alternative visualization to that offered by fluoroscopy.

SUMMARY OF THE INVENTION

In one embodiment of the present invention, a system includes an electromagnetic indicator coil included in a surgical device; and a monitoring unit adapted to detect an electromagnetic field from the electromagnetic indicator coil and display the location and configuration of the electromagnetic indicator coil on a display unit.

In another embodiment of the present invention, a guidewire includes a guidewire shaft; and a plurality of electromagnetic coils spaced longitudinally along the guidewire shaft. Each of the plurality of electromagnetic coils is adapted for generating a corresponding one of a plurality of electromagnetic fields. The plurality of electromagnetic fields jointly defines a configuration of the guidewire shaft.

In still another embodiment of the present invention, a surgical instrument includes at least one electromagnetic coil adapted for generating a corresponding electromagnetic field, which defines a configuration of the surgical instrument.

In yet another embodiment of the present invention, an indicator clip includes fingers for gripping tissue and at least one electromagnetic coil adapted for generating an electromagnetic field detectable by a monitoring system.

In a further embodiment of the present invention, a guidewire system includes a guidewire having a guidewire shaft; multiple electromagnetic coils adapted for generating corresponding electromagnetic fields; a detection unit for generating location data indicative of a relative location of each of the magnetic coils; a data processing unit for transforming the location data into image data representing a configuration of the guidewire shaft; and a display unit for displaying an image representing the configuration of the guidewire shaft.

In a still further embodiment of the present invention, a method is disclosed for monitoring a configuration of a guidewire, in which the guidewire includes a guidewire shaft and multiple electromagnetic coils spaced longitudinally along the shaft; the method including: a) generating an electromagnetic field from each of the electromagnetic coils; b) electromagnetically detecting the electromagnetic fields; c) generating location data indicative of a relative location of each of the magnetic coils; d) transforming the location data into image data representing a configuration of the guidewire shaft; and e) via a display unit, displaying an image representing the configuration of the guidewire shaft.

In a yet further embodiment of the present invention, a surgical method includes: electromagnetically monitoring a guidewire during insertion of the guidewire into a lumen of a body cavity of a patient; using the guidewire to guide a surgical device having an electromagnetic indicator coil; and electromagnetically monitoring the surgical device and the guidewire while guiding the surgical device.

These and other features, aspects and advantages of the present invention will become better understood with reference to the following drawings, description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of a surgical instrument monitoring system, according to one embodiment of the present invention;

FIG. **2**A is a schematic illustration of a guidewire in a looped configuration, in accordance with an embodiment of the present invention;

FIG. **2**B is a schematic illustration of a guidewire in a curved configuration, in accordance with an embodiment of the present invention;

FIG. **3** is an enlarged view of a portion of a guidewire shaft showing a plurality of spaced apart coils, according to an embodiment of the present invention;

FIG. **4**A schematic diagram of a guidewire system showing a guidewire in relation to a guidable device according to an embodiment of the present invention;

FIG. **4**B is a sectional view taken along the line **4**B-**4**B of FIG. **4**A;

FIG. **5** is a flowchart for a method for monitoring guidewire shaft configuration, according to an embodiment of the present invention;

FIG. **6**A is a schematic diagram of an instrument used for placing an indicator clip, according to one embodiment of the present invention;

FIG. **6**B is a schematic diagram of the indicator clip of FIG. **6**A after detachment from the instrument used for placing the indicator clip;

FIG. **7** is a schematic diagram for one example of an instrument-mountable indicator, according to one embodiment of the present invention; and

FIG. **8** is a flowchart for a method of positioning and monitoring the position and configuration of surgical instruments, according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The following detailed description is of the best currently contemplated modes of carrying out the invention. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention, since the scope of the invention is best defined by the appended claims.

Broadly, the present invention provides for monitoring the configuration and positioning of various surgical instruments relative to each other including guidewires, catheters, endoscopes, stents, dilators, and clips that, for example, may be clipped onto a patient's tissue at selective locations. An embodiment of the present invention may be used to monitor guidewire shaft configuration by displaying an image of the guidewire shaft on a display unit. For example, one embodiment of the present invention may be used for monitoring guidewire shaft configuration during an endoscopic procedure, wherein the guidewire shaft may be manipulated with respect to tissues or organs of a patient's body. In addition, embodiments of the present invention provide more general applicability, for example, by allowing the monitoring of surgical instruments other than endoscopes (to which prior art electromagnetic monitoring of surgical instruments has been limited).

The present invention also provides a guidewire, which in contrast to conventional guidewires does not require fluoroscopy to visualize—but instead uses electromagnetic signals emitted from source (indicator) coils on the wire itself—which is detected and displayed on the monitor—so that a configuration of the guidewire shaft may be defined by the plurality of electromagnetic fields. In further contrast to prior designs, a configuration of the guidewire shaft of the present invention may be visualized on a display unit in real time during a procedure while the guidewire shaft is inserted in a patient's body. Unlike the present invention, visualization of conventional guidewires has typically used fluoroscopy, which not only requires bulky equipment, but also may expose both the patient and the surgical team to X-ray irradiation.

Also provided by the present invention is an indicator clip that differs from past designs in that, for example, instead of injecting contrast into the GI tract in order to "tattoo" a certain area which can be visualized on fluoroscopy, the indicator clip can be placed using a clip fixing device to insert the clip through the lumen of the GI tract, and attached to the patient by gripping a portion of the patient's tissue, in order to be placed along the inside of the gastrointestinal tract for marking purposes using electromagnetic field sensing instead of fluoroscopy. The device indicator of the present invention similarly differs from past designs in that devices previously were not marked for radiographic contrast under fluoroscopy, whereas the electromagnetic device indicator provides electromagnetic location information for a device to which it may be attached. Embodiments of the present invention provide an electromagnetic way of marking tissue, devices and guidewires relative to each other.

For example, in one embodiment of the present invention, an indicator clip may be monitored, wherein the indicator clip emits an electromagnetic field and the clip can be placed along the inside of the gastrointestinal tract for marking purposes, e.g., marking the position of an alternated anatomy. In another embodiment, an electromagnetic device indicator may be monitored and is an accessory which can be placed onto any existing endoscope or accessory device. A small profile electromagnetic device indicator can be taped, strapped, or fastened to an endoscope or device (such as a stent deployment catheter or a Stretta radiofrequency catheter, for example). One or several device indicators could be used to locate the positions of multiple devices. Each indicator would individually be seen on a detector monitor. The indicator clip and the electromagnetic device indicator could be used separately or together. For example, for endoscopic stent placement: an electromagnetic indicator clip may be placed at the proximal and distal ends of an esophageal tumor. Then the stent deployment device may have several device indicators which allow for stent deployment at the proper position relative to the indicator clips and the tumor. As another example, for esophageal dilation, the dilator could have two device indicators attached or even embedded into the dilator itself.

FIG. **1** schematically represents a monitoring system **10**, according to one embodiment of the invention. Monitoring system **10** may include a surgical device **20**—such as guidewire **20***a*, surgical instrument **20***b* (e.g., stent or dilator), or indicator clip **20***c*—having one or more electromagnetic indicator coils **30**, also referred to as source coils (also see, for example, FIG. **3**). In the case of guidewire **20***a*, the plurality of electromagnetic indicator coils **30** may be spaced—for example, every 1.0 centimeter (cm)—longitudinally along a guidewire shaft **22** (see also, e.g., FIGS. **2**A-**2**B and FIG. **3**). The plurality of electromagnetic indicator coils **30** may be adapted for generating a corresponding plurality of electromagnetic fields **31**.

Monitoring system **10** may further comprise a power supply unit **40** for providing electrical power to surgical device **20**. Power supply unit **40** may allow passage of an electric current through the plurality of electromagnetic indicator coils **30** for generating the corresponding plurality of electromagnetic fields **31**. In some embodiments, power supply unit **40** may comprise a battery (see FIG. **2**B), or other suitable source of electric current.

Monitoring system **10** may still further comprise a monitoring unit **50**, which may include a detection unit **60**. Detection unit **60** may be adapted for generating location data indicative of a relative location of each of the plurality of electromagnetic indicator coils **30**. The relative location of each of the plurality of electromagnetic indicator coils **30** may be indicated by a relative location of each of the corresponding plurality of electromagnetic fields **31**. As an example, detection unit **60** may include a plurality of detection coils (not shown) for detecting a location of each of the plurality of electromagnetic indicator coils **30**. Monitoring unit **50** may further include a data processing unit **70** for transforming the location data into image data, wherein the image data may represent the configuration of the guidewire shaft **22** or locations and orientations of any of the surgical devices **20**. Data processing unit **70** may comprise a microprocessor or central processing unit (CPU), or a computer, together with suitable software for performing algorithms for transforming the location data into image data. Monitoring unit **50** may still further include a display unit **80** for displaying an image showing the configuration of guidewire shaft **22** or locations and orientations of any of the surgical devices **20**. As an example, the configuration of guidewire shaft **22** may be curved (see FIG. **2**B) or looped (FIG. **2**A). Also the relative positions and configurations of the various surgical devices **20***a*, **20***b*, **20***c*, as shown in FIG. **1**, for example, may be displayed on display unit **80**.

During a procedure involving insertion of a guidewire into a body lumen of a patient, for example, various endoscopic procedures, the guidewire shaft **22** may, unbeknownst to the surgeon, become looped. Looping of guidewire shaft **22** is undesirable, such that the surgeon should become aware of the looped configuration immediately. According to the present invention, the surgeon may visualize the configuration of guidewire shaft **22** in real time while guidewire shaft **22** is inserted in a patient's body. Such a procedure involving insertion of a guidewire into a body lumen of a patient may involve, for example, a guidable instrument such as a catheter or an endoscope, advancement of a dilator (e.g., surgical instrument **20***b*) via the guidewire, or placement of a stent (e.g., surgical instrument **20***b*) via the guidewire.

FIG. **2**A schematically represents a guidewire **20***a* in a looped configuration, according to one embodiment of the invention. Guidewire **20***a* may include a guidewire shaft **22**, having a guidewire distal end **22***a* and a guidewire proximal end **22***b*, and a guidewire handle **24** at proximal end **22***b*. Guidewire shaft **22**, and in particular guidewire distal end **22***a*, may be steerable such that guidewire distal end **22***a* may be guided to a specific location within a body lumen or other part of a patient's body. Visualization of guidewire shaft **22** via display unit **80** may aid the surgeon's attempts to guide distal end **22***a* within the patient's body. Guidewire **20***a* may be electrically coupled to an electrical power source **40'**, which may provide electrical current to electromagnetic indicator coils **30**. Guidewire **20***a* may include a plurality of electrical leads (not shown) for providing electrical current to each of the electromagnetic coils **30**. Guidewire **20***a* may further include a switch **26** for controlling the flow of electrical current to electromagnetic coils **30**.

FIG. **2**B schematically represents a guidewire **20***a* in a curved configuration, also according to one embodiment of the invention. Guidewire **20***a* may include a guidewire shaft **22**, having a guidewire distal end **22***a* and a guidewire proximal end **22***b*, and a guidewire handle **24** at proximal end **22***b*, generally as described with reference to FIG. **2**A. Guidewire **20***a* may further include a battery **40"**, which may provide electrical current to electromagnetic indicator coils **30**, and switch **26** for controlling the flow of electrical current to electromagnetic coils indicator **30**.

FIG. **3** shows a portion of a guidewire shaft **22** including spaced apart coils **32***a*, **32***b*. Coils **32***a*, **32***b* may be spaced longitudinally along guidewire shaft **22**. The shape or geometry of coils **32***a*, **32***b*, and their size relative to the size of guidewire shaft **22**, may be other than that shown in FIG. **3**. For example, FIG. **3** may not be drawn to scale. Although only two coils **32***a*, **32***b* are shown in FIG. **3**, a larger number of coils may be used in accordance with embodiments of the invention. The number of coils and their spacing on guidewire shaft **22** may be, at least to some extent, a matter of design choice. Guidewire shaft **22** may have a diameter, D, typically in the range from about 0.02 to 0.08 inches, usually from about 0.025 to 0.07 inches, and often from about 0.03 to 0.05 inches.

FIG. **4**A schematically represents a guidewire system **100**, which may include a guidewire **20***a* shown in relation to a guidable device **90**. Guidable device **90** may be, for example, a catheter or an endoscope. Guidable device **90** may include a shaft **92**, having a distal end **92***a* and a proximal end **92***b*, and a handle **94** at proximal end **92***b*. Guidewire system **100** may be used in conjunction with a monitoring unit **50** (see FIG. **1**) for visualizing the configuration of guidewire shaft **22** in real time.

FIG. **4**B shows a sectional view of shaft **92** taken along the line **4**B-**4**B of FIG. **4**A. Shaft **92** may have a lumen or working channel **93**, which may extend the entire length of shaft **92**. Lumen **93** may be capable of movably receiving guidewire shaft **22** so that guidewire shaft **22** may be advanced or retracted longitudinally relative to shaft **92** within lumen **93**. Guidewire **20***a* of FIGS. **4**A-**4**B may have elements and features as described with reference to FIGS. **1**-**3**. In some embodiments, guidewire handle **24** may be removable from guidewire shaft **22**, such that after advancing guidewire **20***a* into a specific location within a patient's body, guidewire handle **24** may be removed to allow guidable device **90** to be advanced along guidewire shaft **22**. Guidable device **90** may further include a fitment **96**, through which an ancillary device (not shown) may be passed via lumen **93**. Ancillary devices may include, for example, forceps, dilators, fluid and vacuum lines, and the like. In embodiments where guidable device **90** may comprise an endoscope, an eyepiece **98** may be included, together with associated components, such as optical fibers, a light source, and the like.

In some embodiments, guidable device **90** may include a second set of electromagnetic indicator coils **30**, whereby both guidable device **90** and guidewire shaft **22** may be visualized together on a display unit in the absence of fluoroscopy (exposure to X-rays), wherein an image of guidable device **90** may be distinguished from an image of guidewire shaft **22**, for example, based on a color difference or line difference (e.g., a broken line versus a solid line).

Guidewire system **100** (FIGS. **4**A-**4**B), guidewires **20***a* (FIGS. **2**A-**2**B), and guidewire monitoring system **10** (FIG. **1**) may provide greater flexibility of application and be more generally useful than technology that is limited only to endoscopes such as the ScopeGuide™ apparatus. For example, a guidewire **20***a*may be passed within the working channel of any flexible endoscope, and may be advanced distally beyond the endoscope in order to guide either advancement of the endoscope or advancement of another accessory device. As an example, during routine colonoscopy an acute angle may be encountered which does not allow the colonoscope to freely advance, in which event the physician may advance guidewire **20***a* through the working channel or lumen of the colonoscope beyond the acute angle while observing the configuration of guidewire **20***a* on display unit **80**. A section of greater flexibility (e.g., less stiffness) near the distal end of the guidewire can aid in this maneuver. Thereafter, the colonoscope may be advanced over guidewire **20***a* by pushing the endoscope while holding the guidewire. A guidewire **20***a* of one embodiment may also be used in a similar manner during upper endoscopy, e.g., in situations where there is an alternated anatomy (e.g., Billroth operation II anastomosis).

Furthermore, guidewire **20***a* of the present invention may be used in conjunction with a surgical instrument **20***b* as shown in FIG. **1**—such as a dilator (e.g., dilator **720** in FIG. **7**) which may itself include a plurality of electromagnetic indicator coils **30** to allow visualization of the surgical instrument **20***b*, (e.g., dilator **720**) during a procedure. Still further, a surgical instrument **20***b*, which may be, for example, a jejunostomy tube (not shown), may be equipped with a plurality of electromagnetic coils **30** to allow visualization of the jejunostomy tube (surgical instrument **20***b*) during endoscopic placement of gastrojejunostomy.

FIG. **5** schematically represents a series of steps involved in a method **200** for monitoring the configuration of a guidewire shaft and/or ancillary device (such as a stent, dilator, or jejunostomy tube, for example) in the absence of fluoroscopy, according to another embodiment of the invention, wherein step **202** may involve manipulating a guidewire shaft. As an example, step **202** may involve manipulating a guidewire shaft towards a specific location within a patient's body during a procedure. Alternatively, step **202** may involve manipulating a guidewire shaft during a training session for training an intern or trainee surgeon or other medical personnel. The guidewire shaft may be coupled to a guidewire handle, and the guidewire shaft may be steerable, e.g., within a body lumen, via the guidewire handle.

Step **202** may involve advancing the guidewire shaft through a working channel or lumen of an endoscope or catheter, wherein the endoscope or catheter is pre-positioned within a body lumen. As an example, the body lumen may be a blood vessel, a colon, a fallopian tube, and the like. Alternatively, step **202** may involve advancing the guidewire shaft through a body lumen to a specific location within the body lumen, wherein the guidewire serves to subsequently guide an endoscope or catheter over the guidewire shaft to the specific location within the body lumen, for example, according to the Seldinger technique. The guidewire shaft may include a plurality of electromagnetic coils spaced longitudinally along the guidewire shaft. In a further embodiment, step **202** may involve advancing an ancillary device, such as a dilator, stent, and the like, over the guidewire shaft, wherein the ancillary device may be equipped with a plurality of electromagnetic indicator coils **30** to allow visualization of the position and configuration of the ancillary device.

Step **204** may involve generating a plurality of electromagnetic fields corresponding to the plurality electromagnetic coils arranged on the guidewire shaft. The plurality of electromagnetic fields may be generated by passing an electric current through each of the plurality electromagnetic coils on the guidewire shaft.

Step **206** may involve generating or providing location data indicative of the relative location of each of the plurality of electromagnetic coils. The location data may be indicative of a direction and a distance from the detector (e.g., detector unit **60**) of each of the corresponding plurality of electromagnetic fields generated by the plurality of electromagnetic coils. The location data may be provided via a detection unit or sensor for detecting the plurality of electromagnetic fields.

Step **208** may involve transforming the location data generated in step **206** into image-related data representing a configuration of the guidewire shaft. Step **208** may involve transforming the location data via a data processing unit. The location data generated in step **206** may be transformed into image-related data using a microprocessor or central processing unit (CPU), or a computer.

Thereafter, step **210** may involve displaying an image showing the configuration of the guidewire shaft. Step **210** may involve displaying the configuration of the guidewire shaft on a display unit, which may comprise a liquid crystal display (LCD), cathode ray tube (CRT), or TV monitor, and the like, whereby the surgeon or other member of the team may readily visualize the image of the guidewire shaft. As an example, by displaying an image showing the configuration of the guidewire shaft in step **210**, the surgeon may immediately determine whether the guidewire shaft has adopted a looped (generally undesirable) configuration, thereby allowing measures to be taken to change (correct) the configuration of the guidewire shaft.

After the surgeon has visualized the configuration of the guidewire shaft, the guidewire shaft may again be manipulated (step **202**), as appropriate, responsive to an observed guidewire shaft configuration (step **210**).

Embodiments of the present invention may also be used with other devices, such as an ancillary device (e.g., surgical instrument **20***b*) that may be guided to a specific location (which may be marked, e.g., using indicator clips **20***c*) within a patient's body via a guidewire (e.g., guidewire **20***a*). For example, a device such as a dilator, a jejunostomy tube, or a stent may include a plurality of electromagnetic indicator coils **30** which may allow visualization of the dilator or stent on a display unit, e.g., as described with reference to FIGS. **1-5**, in the absence of fluoroscopy. The guidewire may be a conventional guidewire or guidewire **20***a*according to an embodiment of the invention. In this way, a stent or other device may be placed in an occluded lumen or vessel without exposure to X-rays.

FIG. **7**B shows one such possible example of a dilator **720** having embedded indicator coils **30** located, for example, toward a proximal end **724** of dilator **720** and toward a distal end **722** of dilator **720**. Indicator coils **30** may be embedded in dilator **720**, for example, by being integrally formed into the dilator **720** during its fabrication.

In an alternative embodiment, an indicator coil **30** of device indicator **700** may be provided with straps **734**—as shown in FIG. **7**A—for attachment to a device—such as dilator **720**—or other surgical instrument **20***b*. Straps **734** may be provided with adhesive, for example; or may possess a combination of flexibility and stiffness that allows them to be deformed around a surgical instrument **20***b* yet retain a grip on instrument **20***b*; or an indicator coil **30** could be bonded to an instrument **20***b* with or without straps **734**, for example. Device indicator **700** (as well as dilator **720** or other surgical instrument **20***b*) may be provided with a power source **40***a*. Power source **40***a* may include, for example, an antenna, a capacitive discharge device, or a battery. Power source **40***a* may be self-contained by the device indicator **700** or surgical instrument **20***b* (such as dilator **720**) as shown in FIGS. **7**A-**7**B. In an alternative embodiment, a power source **40***b* may be provided that is external and connected by wire **41** to the surgical instrument **20***b* or indicator clip **20***c*, as shown in FIG. **6**B. It is desirable that the power sources **40***a* or **40***b* be capable of providing an electromagnetic field **31** detectable by detection unit **60** for about 1.0 hour.

FIG. **6**A shows a clip fixing device **600** for placing an indicator clip **20***c*, for example, in the lumen of a body cavity of a patient. Clip fixing device **600** may include a handle **602** with a plunger **604**. Activating plunger **604** may close fingers **606** (see also FIG. **6**B) so that indicator clip **20***c* may be attached, for example, to a portion of tissue within a patient. Further activation of plunger **604** may separate indicator clip **20***c* from clip fixing device **600**, allowing clip fixing device to be withdrawn, for example, from a patient. Clip fixing device **600** may have a shaft **608** adapted for guiding the indicator clip **20***c* to a desired location. Shaft **608** may include a plurality of electromagnetic indicator coils **30** which may be used for monitoring and guiding shaft **608** as in the case of guidewire **20***a*. Clip fixing device **600** may also be used in conjunction with guidewire **20***a* for monitoring the position and configuration of shaft **608** and indicator clip **20***c*. Indicator **20***c* may include one or more electromagnetic indicator coils **30**, which may be fastened to or formed with the indicator clip **20***c* as described for the case of a device indicator **700**. Indicator **20***c* may also include a power source **40***a* as described for the case of a device indicator **700**.

FIG. **8** illustrates method **300** for fluoroscopy-free, electromagnetic monitoring and guiding of surgical implements including guidewires, device indicators, and indicator clips in accordance with embodiments of the present invention. Surgical method **300** may include a step **302** of electromagnetically monitoring a guidewire—such as guidewire **20***a*—during insertion of the guidewire into a lumen of a body cavity of a patient (not shown). Method **300** may include a step **304** of using the guidewire to guide a surgical device—including but not limited to stents, catheters, endoscopes, jejunostomy tubes, and dilators as well as other ancillary devices. In addition, step **304** may include guiding the shaft (e.g., shaft **608**) of a clip fixing device—such as clip fixing device **600**—through the lumen of a body cavity of a patient for attaching an indicator clip **20***c* as a location marker in the patient. The surgical device may have an electromagnetic indicator coil **30**, such as illustrated by dilator **720**. A device indicator **700** may be attached to a conventional surgical device to convert it to an electromagnetically monitorable surgical device—such as a surgical instrument **20***b*. Method **300** may include step **306**, which may be accomplished simultaneously with the other steps, of electromagnetically monitoring the surgical device (e.g. surgical device **20**, including guidewires **20***a*, surgical instruments **20***b*, and indicator clips **20***c*) and the guidewire while guiding the surgical device. Thus, a guidewire, a surgical instrument, and an indicator clip may all be electromagnetically monitored simultaneously in regard to location of each relative to the others and the overall configuration of each relative to the others.

For example, it may be desired to place dilator **720** in between two indicator clips **20***c* that have previously been placed as markers at proximal and distal ends of a restricted section of a body lumen. A guidewire **20***a* may be inserted until its distal end reaches the distal marker and the relative positions of the guidewire **20***a* and markers monitored. The dilator **720** may then be advanced until its distal end **722** reaches the proximal marker. The desired overall configuration of guidewire, dilator, and markers, however, is that the dilator **720** should be advanced along the guidewire **20***a* until the dilator **720** is situated between the proximal and distal markers with the distal end **722** near the distal marker and the proximal end **724** near the proximal marker. The surgeon can advance the dilator **720** along the guidewire **20***a*, electromagnetically monitoring the positions of all the devices relative to each other until the desired overall configuration of the guidewire **20***a*, dilator **720**, and markers **20***c* is achieved. The guidewire **20***a* may then be removed.

Step **308** of method **300** includes the novel operation that one or more indicator clips—such as indicator clip **20***c*—can be placed at a selected location within a patient and its position monitored in conjunction with monitoring the position of another surgical device **20**—such as surgical instrument dilator **720**—to precisely position and monitor the location of the surgical device (e.g. dilator **720**) relative to the position(s) and location(s) of the marker indicator clip or clips **20***c*.

It should be understood, of course, that the foregoing relates to exemplary embodiments of the invention and that modifications may be made without departing from the spirit and scope of the invention as set forth in the following claims.

I claim:

1. A system comprising:

a guidewire having two or more electromagnetic indicator coils positioned thereon, including a first set and a second set of electromagnetic coils, the indicator coils configured to produce electromagnetic fields;

a guidable surgical device having one or more of the electromagnetic indicator coils positioned thereon;

a monitoring unit adapted to detect electromagnetic fields from said electromagnetic indicator coils;

an indicator clip having a power source and being attached to the guidewire, wherein the indicator clip has one of the electromagnetic indicator coils positioned thereon;

and a display unit configured to display the location and configurations of said guidewire and said guidable surgical device.

2. The system of claim **1**, wherein said display unit displays the location of said indicator clip.

3. The system of claim **1** wherein said monitoring unit detects each corresponding electromagnetic field of the electromagnetic indicator coils individually to display the configuration of said surgical device and said guidewire.

4. The system of claim **1** further comprising:

a plurality of indicator clips; and

a plurality of instances of said guidable surgical device;

the indicator clips and the guidable surgical devices having at least one of the electromagnetic indicator coils positioned thereon in addition to the indicator clips being positioned on the guidewire; and

said display unit displays the location of said indicator clips and surgical instruments.

5. A guidewire system, comprising:

a guidable device including an indicator clip having a plurality of fingers;

a controller configured to close the plurality of fingers and to separate the indicator clip from the guidewire system;

a guidewire attached to the guidable device, the guidewire including a guidewire shaft;

a removable handle attached to the guidable device;

electromagnetic coils positioned on the guidable device and spaced longitudinally on said guidewire shaft, said electromagnetic coils being adapted for generating a plurality of electromagnetic fields;

a detection unit for generating location data indicative of a relative location of each of said electromagnetic coils;

a data processing unit for transforming said location data into image data representing a configuration of said guidewire shaft; and

a display unit for displaying an image representing said configuration of said guidewire shaft and an image of the guidable device so that the image of the guidable device is distinguishable from an image of guidewire shaft based on color difference.

6. The guidewire system of claim **5**, wherein the guidable device is a catheter having a catheter lumen for movably receiving said guidewire shaft.

7. The guidewire system of claim **5**, wherein the guidable device is an endoscope having an endoscope lumen for movably receiving said guidewire shaft.

8. The guidewire system of claim **5**, wherein:

said indicator clip includes at least one of the electromagnetic coils adapted for generating a plurality of electromagnetic field;

said data processing unit also transforms said location data into image data representing a configuration of said indicator clip; and said display unit displays an image representing said configuration of said guidewire shaft and said indicator clip.

9. An instrument comprising:

a surgical instrument chosen from one of a dilator, a stent, a catheter, and a jejunostomy tube;

a plurality of electromagnetic coils including a first set and a second set of electromagnetic coils included in the surgical instrument, each of said plurality of electromagnetic coils being adapted for generating a corresponding one of a plurality of electromagnetic fields, and

said plurality of electromagnetic fields jointly defining a configuration of said surgical instrument, and

said plurality of electromagnetic coils being separable from said surgical instrument by a controller.

10. A method for monitoring a configuration of a guidewire and a guidable device, comprising:

generating electromagnetic fields from a plurality of electromagnetic coils spaced longitudinally along a shaft of the guidewire and from one or more of the electromagnetic coils positioned on the guidable device, wherein each of the electromagnetic coils is attached to a clip with a power source;

electromagnetically detecting said electromagnetic fields from the shaft and from the guidable device;

generating location data indicative of a relative location of each of said electromagnetic coils;

transforming said location data into image data representing a configuration of said guidewire shaft and the guidable device; and

via a display unit, displaying an image representing said configuration of said guidewire shaft and the guidable device so that the image of the guidable device is distinguishable from an image of the guidewire shaft;

wherein the image of the guidewire shaft and the image of the guidable device are distinguishable based on whether a broken line versus a solid line is used on the guidewire shaft and the guidable device.

11. The method of claim **10**, wherein the image of the guidewire shaft and the image of the guidable device are distinguishable based on color.

12. The method of claim **10**, wherein:

said image is based on said image data provided in said step (d); and

said location data provided in said step (c) is based on said electromagnetic detection provided in said step (b).

13. A surgical method comprising:

electromagnetically monitoring a guidewire during insertion of the guidewire into a lumen of a body cavity of a patient;

using the guidewire to guide a surgical device having an electromagnetic indicator coil; and

electromagnetically monitoring the surgical device and the guidewire while guiding the surgical device,

wherein electromagnetically monitoring includes producing electromagnetic fields within the patient with the guidewire including indicator coils positioned on the guidewire and the surgical device while displaying the guidewire and the surgical device to distinguish them by color, or by whether a broken line versus a solid line is used on the guidewire and the surgical device; and

placing an indicator clip having a power source and marking a location in the lumen of a patient using a plurality of the indicator coils.

14. The method of claim **13**, further including:

electromagnetically monitoring the relative locations of the surgical device and the indicator clip.

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